VA Medical Center

Consent for Clinical Procedure

A. IDENTIFICATION

1. Patient name, Social Security Number, and Date of Birth:

| 2. Decision-making capacity: | | | | | |
|------------------------------|--|--|--|--|--|
| □ Yes | | | | | |
| \square No | | | | | |

3. Name of the treatment(s)/procedure(s):

Long-term video EEG monitoring

4. Part of the body on which the treatment/procedure will be performed:

Sensors called electrodes will be attached to your head, scalp, facial area, limbs and/or torso. You will have an IV access device placed.

- 5. Practitioner obtaining consent:
- 6. Supervising practitioner:
- 7. Additional practitioner(s) performing or supervising the treatment/procedure:

B. INFORMATION ABOUT THE TREATMENT/PROCEDURE

8. Reason for treatment/procedure (diagnosis, condition, or indication):

Characterization of events, aid in possible diagnosis of epilepsy

9. Brief description of the procedure:

This procedure involves monitoring you 24 hours a day using sensors called electrodes, and audio and video recording. You will be observed during normal activity and during any event that occurs. Methods such as sleep deprivation, hyperventilation and strobe lights may be used to induce an event. If you are taking medicines, they may be reduced or stopped.

Electrodes will be placed on your head and may be attached to your limbs or torso. They will record electrical activity in the brain. Your heart rate, blood pressure and breathing may also be recorded. You will be asked to wear a transmitter, a small box that electrodes are plugged into. This device stores and sends information to a computer. Information from recordings will be analyzed.

The electrodes on your head are attached with special "glue", called collodion (paste may be used if you cannot tolerate collodion), which holds the electrodes in place for an extended period of time. The collodion may cause your scalp to itch. You should not scratch around the electrodes as they may become loose and not record brain activity. Please let the nurse know if you need some medication to relieve the itching. You will not be able to shower while the electrodes are on your head but you may sponge bathe.

At the end of your stay the electrodes and your IV access device will be removed.

Photographs and videos may be taken of this procedure and that my video EEG monitoring data may be viewed by various staff involved in clinical care, research or education.

10. Potential benefits of the treatment/procedure:

This procedure may help your doctor determine the nature of your events.

In some patients the procedure will not detect the cause or origin of the events or any events at all.

11. Known risks and side effects of the procedure:

Known risks of this procedure include, but are not limited to:

- Headache
- Discomfort and skin irritation from electrodes
- Skin Irritation and tenderness around IV site
- Events (could be stronger, longer, or different in type)
- Injury from an event
- Electric shock if the transmitter gets wet

12. Alternatives to the treatment/procedure:

You can choose not to have this procedure and follow-up with your provider.

13. Anesthesia / Moderate Sedation:

Neither anesthesia nor moderate sedation will be used in this procedure unless your provider determines that it is important for your care.

14. Blood products:

It is not expected that blood products will be used in this treatment/procedure.

15. Additional information:

16. Comments:

C. SIGNATURES

Practitioner obtaining consent:

- All relevant aspects of the procedure and the alternative not to have the procedure have been discussed with the patient (or surrogate) in language that s/he could understand. This discussion included the alternative to follow-up with the provider.
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this treatment.
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

| Signature o | f health | care profes | ssional: _ | | |
|-------------|----------|-------------|------------|------|--|
| Date/Time: | | | | | |

Patient or surrogate:

By signing below, I attest to the following:

- Someone has explained this procedure and what it is for.
- Someone has explained how this procedure could help me, and I understand the risks and side effects of the procedure.
- -Someone has answered all my questions
- -I know that I may refuse or change my mind at any time about having this procedure. If I do refuse or change my mind, I will not lose my health care or any other VA benefits
- -I have been offered the opportunity to read the consent form
- -I choose to have this procedure.

| Signature of patient or surrogate Date/Time: | |
|---|--|
| Witnesses: No witness is required if the patient or surrogrequired only when the patient's signature is i mark. | rate signs his/her name. Two witnesses are indicated with an "X" or some other identifying |
| If witnesses are required: | |
| | Date/Time: |
| | Data/Timo: |